IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	10/081,641
Appellant:	Patrick A. Haverkost; James Weldon; Karen McDonald; Paul F. Chouinard; Wade M. Johnson
Filed:	February 22, 2002
Title:	METHOD AND APPARATUS FOR DEPLOYMENT OF AN ENDOLUMINAL DEVICE
TC/A.U.:	3731
Examiner:	Sarah Webb
Confirmation No.:	2371
Notice of Appeal Filed:	February 27, 2006
Docket No.:	BSI-486US

APPEAL BRIEF

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S I R :

In response to the Final Official Action dated September 29, 2005, Appellants are submitting this Appeal Brief for the above-identified application.

I. REAL PARTY IN INTEREST

The Real Party in Interest in this matter is Boston Scientific SCIMED, Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants, Appellants' legal representative, or Assignee which may be related to, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1 and 3-51 are pending. Claims 9, 12-16, 18-29, 34-46, and 48-50 have been withdrawn from consideration. Claims 1, 3-8, 10, 11, 17, 30-33, 47, and 51 have

been rejected and are appealed. Claims 1, 3-8, 10, 11, 17, 30, 47 and 51 stand or fall together, and claims 31 and 33 stand or fall together. Claims 1, 31, and 47 are each separately discussed in this brief. Claims 1 and 47 are independent claims.

IV. STATUS OF AMENDMENTS

The present application is under final rejection. A Final Office Action of September 29, 2005 rejected all claims. In response, Appellants submitted an Amendment under 37 C.F.R. § 1.116 on November 17, 2005 that included claim amendments and supporting remarks distinguishing the amended claims from the cited prior art. In that Amendment, Appellants sought an amendment to their claim 1 to recite that the claimed introducer included an "anchoring means... for anchoring the endoluminal device proximal end" that is configured to anchor the proximal end "outside the introducer and against the body lumen." However, an Advisory Action of December 13, 2005, refused entry of that Amendment, alleging that it did not "place the application in better form for appeal by materially reducing or simplifying the issues for appeal."

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claims 1, 31, and 47 are specifically discussed in this appeal. The claims are generally directed to an improved introducer for the delivery of an endoluminal device (e.g. a stent) in a body lumen (e.g. an artery). Among other features, the claimed introducer is equipped with two outer sheaths - a forward, "anterograde," sheath and a rear, "retrograde," sheath. The claimed introducer is further equipped with an anchoring means beneath one of these sheaths for fixing a endoluminal device while the device is deployed beginning from its proximal end (from the perspective of the implanting surgeon) towards its distal end (referred to herein as "reverse deployment" as compared to traditional distal-end-first deployment).

In accordance with 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in claims 1, 31, and 47, the claims being appealed, is set forth below. The various structural elements of Appellants' invention as claimed are further identified by the accompanying reference number corresponding to the reference number shown in Appellants' Figures. Citations to the application's support for claimed subject matter are made by reference to page (*p.*) and line (*l.*) of Appellants' specification (*AS*) as originally filed (e.g., *AS p. 1, l. 22 - p. 2, l. 9*) as well as corresponding figures (*Figs.*).

Claim 1

Independent claim 1 broadly recites an introducer 100, 600. *See, generally, AS p. 3, l. 18-20; p. 11, l. 26-29; Figs. 2 and 6.* The claimed introducer 100,600 has an anterograde portion 104 and a retrograde portion 102 and comprises a shaft 106 having a distal tip 124 (*AS p. 8, l. 15-18; p. 11, l. 26-29*); an inner sheath 116 mounted concentrically over the shaft 106 (*AS p. 7, l. 22-24; p. 11, l. 26-29*); an anterograde sheath 126 attached to the distal tip 124 (*AS p. 8, l. 15-18; p 11. l. 29-30*); and an anchoring means 120 in at least one of the retrograde 102 and anterograde 104 portions for anchoring the proximal end 131 of the endoluminal device 130 after expansion of the proximal end 131 in the body lumen **and** for minimizing relative axial movement between the proximal end 131 of endoluminal device 130 and the body lumen. *AS p. 8, l. 6-12; p. 10, l. 16 - p. 11, 15; p. 11, l. 26 - p. 12, l. 17; p. 12, l. 24 - p. 14, l. 2; Figs. 4A, 4B, 5A, 5C, 7.*

Appellants' "anchoring means" recited in claim 1 properly invokes the means plus function provision of 35 U.S.C. § 112, ¶ 6 to identify balloon 120 shown (un-inflated) in Appellants' Figures 2 and 7, or tether 152 shown in Appellants' Figures 5A and 5C, or proximally extended endoluminal device portion 131a in combination with notch 150 shown in Appellants' Figures 4A and 4B, and equivalent structures thereto. Balloon 120 is described in a first introducer embodiment 100 at page 8, lines 6-12 of the Appellants'

specification as originally filed and in a second introducer embodiment 600 at page 12, lines 9-17. Tether 152 is described at page 10, line 29 through page 11, line 15. Extended device portion 131a together with notch 150 is described at page 10 lines 16-28. Appellants' disclosed anchoring means achieve **both** of the limitations recited in Appellants' claim 1: (1) anchoring the proximal end of the endoluminal device after expansion of the proximal end into the expanded configuration in the body lumen; and (2) minimizing relative axial movement between the device and the body lumen. All of the above structures recited by the applicants may be used to fix the proximal end of the endoluminal device after it has been expanded into the body lumen, and by so fixing that expanded end, thereby minimize relative axial movement between the device and the body lumen.

Claim 31

Claim 31 depends from claim 30 which, in turn depends from claim 1. Claim 31 therefore incorporates the limitations of both claim 1 and 30. In addition to the features recited in claim 1, above, the introducer of claim 31 further comprises a proximally retractable retrograde sheath 112, mounted concentrically over its shaft 106 and inner sheath 116, that extends axially over the proximal end of the endoluminal device. *AS p. 7, l. 20-28.* The anterograde portion 104, in this embodiment, extends over a greater length of the endoluminal device 600 than the retrograde portion 102. *Fig. 6.*

Claim 31 indirectly depends from claim 1 and therefore incorporates the "anchoring means" limitation recited in claim 1. As noted in the Appellants' summary of the subject matter of claim 1, that claim properly invokes the means plus function provision of 35 U.S.C. § 112, ¶ 6 to identify balloon 120, or tether 152, or extended portion 131a in combination with notch 150, and equivalent structures thereof.

Claim 47

Independent claim 47 also broadly recites an introducer 100, 600. *See, generally, AS p. 3, l. 18-20; p. 11, l. 26-29; Fig 2.* The claimed introducer 100, 600 comprises a retrograde portion 102 and an anterograde portion 104 (*AS p. 7, l. 21-22*); a shaft 106 (*AS p. 7, l. 22-24*); an endoluminal device 130 (*AS p. 8, l. 9-12*); and an inflatable balloon 120 (*AS p. 8, l. 6-12; Fig. 2*). The inflatable balloon 120 is mounted radially inside the retrograde portion 120 and sized to anchor the endoluminal device proximal end 131 against the body lumen after expansion of its proximal end 131 to minimize axial movement of the device relative to the body lumen during the device's unsheathing. *AS p. 9, l. 12-14; Fig. 2.*

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3-8, 10, 11, 17, 30, 32, 47, and 51 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,201,757 to Heyn et al. (hereinafter, "Heyn") in view of U.S. Patent No. 6,042,589 to Marianne (hereinafter, "Marianne").

Claims 31 and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Heyn in view of U.S. Patent No. U.S. Patent No. 5,445,646 to Euteneuer (hereinafter, "Euteneuer").

VII. ARGUMENT

A. ARGUMENT SUMMARY

Appellants challenge each of the obviousness rejections advanced by the Final Office Action for failure to establish a proper case of prima facie obviousness. The rejection of claims 1, 3-8, 10, 11, 17, 30, 32, 47, and 51 is premised upon the proposed combination of

Heyn and Marianne. The Office Action, however, fails to properly articulate a suggestion or motivation to combine the reference teachings in the manner advanced by the Office Action. Moreover, there are aspects of each of those disclosures that would militate against their combination. The rejection of claim 31 and 33, premised upon the proposed combination of Heyn with Euteneuer, fails to teach all of the limitations of Appellants' claims.

Appellants set forth, in the detailed arguments sections identified as E and F, below, their challenge to each rejection of the Office Action.

B. ISSUE

All the appealed claims stand rejected under 35 U.S.C. § 103 as unpatentable by the disclosure of Heyn in view of Marianne or the disclosure of Heyn in view of Euteneuer. These are the only rejections; there are no other rejections and no other applied references. The issue on appeal is whether the cited combination of references renders Appellants' claimed invention obvious.

C. LEGAL STANDARD

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> ...
>
> 35 U.S.C. § 103.

Obviousness is analyzed using the four step analysis promulgated in *Graham v. John Deere. Graham v. John Deere,* 148 USPQ 459, 467 (1966). As set forth in the M.P.E.P. § 2141(II), when applying 35 U.S.C. § 103, the following framework must be adhered to:

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

When obviousness is based on a combination of references, the references must be analogous art. *In re Clay*, 23 USPQ2d 1058, 1060 (Fed. Cir. 1992). Art is analogous if the art is from either (1) the same field of endeavor, regardless of the problem addressed; or (2) a different field of endeavor, but is reasonably pertinent to the particular problem with which the inventor is involved. *Id*. Motivation to combine the references must be shown. *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998); *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Moreover, "[t]he showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence." *Teleflex, Inc. v. Ficosa North Am. Corp.*, 63 USPQ2d 1374 (Fed. Cir. 2002).

D. CLAIMS 1, 3-8, 10, 11, 17, 30, 32, and 51

(1) APPELLANTS' CLAIM LIMITATION RECITING "ANCHORING MEANS... FOR ANCHORING THE ENDOLUMINAL DEVICE... AND FOR MINIMIZING RELATIVE AXIAL MOVEMENT BETWEEN THE PROXIMAL END OF THE DEVICE AND THE BODY LUMEN" IS A VALID STRUCTURAL CLAIM LIMITATION ENTITLED TO PATENTABLE WEIGHT

35 U.S.C. § 112, paragraph 6 (§ 112, ¶6) permits patent applicants express structural limitations as "means for" performing one or more functions:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, an such claim shall be construed to cover the corresponding

structure, material, or acts described in the specification an equivalents thereof.

Appellants' claim 1, as appealed, is set forth below:

1. An introducer, having a retrograde portion and an anterograde portion, for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration, the introducer comprising:

a shaft having a distal tip;

an inner sheath mounted concentrically over the shaft, wherein the endoluminal device is mounted concentrically over the inner sheath in ~~a~~ the compressed configuration;

an anterograde sheath attached proximally to the distal tip, mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder; and

anchoring means in at least one of the retrograde portion or the anterograde portion for anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen and for minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end.

The final limitation recited by appealed claim 1 is presented in proper "means for" language within the ambit of 35 U.S.C. § 112, paragraph 6 ("§ 112, ¶ 6"). *See Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308 (Fed. Cir. 1999) ("[I]f the word 'means' appears in a claim element in combination with a function, it is presumed to be a means-plus-function element to which § 112, ¶ 6 applies.") Accordingly, the limitation invokes **structural features**, i.e. "anchoring means," both "for anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration ..." and "for minimizing relative axial movement between the proximal end of the device and the body lumen." Remarks included with the Office Action of September 29, 2005 suggest that the Examiner has not appreciated that the Appellants' limitations are properly structural under § 112, ¶ 6.

> Applicant's arguments are based on the intended use of the device. The claims recited language directed toward the intended method of deployment of the stent using the introducer, such as "anchoring the endoluminal device proximal end after expansion of the proximal end" and "minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end." A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

The Advisory Action of December 13, 2006, reiterated the Examiner's flawed position in remarking, again, that "[p]art of Applicant's argument is directed toward the intended use of the device which is not explicitly disclosed by the prior art, although the modified Heyn device is capable of being deployed by the steps recited in the claims."

Despite the Examiner's position to the contrary, Appellants' "anchoring means" involves a valid structural limitation and is entitled to patentable weight.

(2) THE DISCLOSURE OF HEYN CANNOT RENDER APPELLANTS' CLAIM 1 OBVIOUS BECAUSE IT FAILS TO TEACH OR SUGGEST AN "ANCHORING MEANS... FOR MINIMIZING RELATIVE AXIAL MOVEMENT BETWEEN THE PROXIMAL END OF THE DEVICE AND THE BODY LUMEN"

As a preliminary matter, it is unclear based upon the record whether Appellants' claim 1 stands rejected based upon Heyn alone or Heyn in combination with Marianne. The Final Office Action implied that the rejection was based on Heyn alone because it identified Heyn as the primary reference and did not cite to Marianne until it acknowledged that Heyn "fails to form the anchoring means as a balloon." OA, p. 2. Appellants' claim 1 does not recite a balloon. It is Appellant's other independent claim, claim 47, that recites a balloon. Appellants therefore understand the obviousness rejection of their claim 1 to be based upon Heyn alone.

The later Advisory Action, identified above, however, suggested that Appellants' claim 1 may stand rejected based upon the proposed combination of Heyn and Marianne

because it referred to a "modified Heyn" device in the context of addressing Apellants' "anchoring means" limitation:

> **The function of the anchoring means** is to anchor the proximal end of the stent, which is met by the prior art. Part of Applicant's argument is directed toward the intended use of the device which is not explicitly disclosed by the prior art, although the **modified Heyn device** is capable of being deployed by the steps recited in the claims.

So that the patentability of these claims may be resolved by a final decision from the Board, Appellants have endeavored to address both of the potential rejections in this section (E) and the section to immediately follow (F).

In rejecting Appellants' claim 1, the Final Office Action alleges that Heyn discloses a stent introducer that includes a shaft with a distal tip, inner sheath, stent, anterograde sheath attached to the distal tip, and a retrograde sheath. *OA, p. 2.* It also contends that Heyn teaches that the anterograde sheath and the retrograde are moveable between the positions of abutting one another and being laterally spaced from one another. *Id.* Further, Heyn's anterograde sheath is purportedly axially moveable in a distal direction by distally moving the shaft since the sheath is connected to the shaft by way of distal tip. *Id.* Finally, the Office Action argues that Heyn also includes an anchoring means in the form of detent in the retrograde portion of preventing axial movement of the stent. *Id.*

Appellants respectfully submit, however, that Heyn is devoid of any teaching or suggestion of a device feature (i.e. an anchoring means) that (1) anchors the endoluminal device proximal end after expansion of the proximal end into the proximal configuration in the body lumen and (2) minimizes relative axial movement between the proximal end of the device and the body lumen as recited in the last limitation of Appellant's claim 1:

> ...**anchoring means** in at least one of the retrograde portion or the anterograde portion **for anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen**

and

for minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end.

Heyn teaches the inclusion of "detents" in a delivery device to "prevent any substantial axial travel of the stent relative to the intermediate catheter" underlying the stent. Heyn, col. 6, lines 50-54. Heyn teaches, generally, that during deployment of a self-expanding stent, outer distal and proximal sleeves are axially retracted to release its stent. The detents function passively to prevent the stent from migrating axially in response to friction between the stent and the outer sleeves during retraction of the sleeves. Once the outer sleeves are fully retracted, the stent is deployed. The detents taught by Heyn do not, indeed cannot, anchor the proximal end of its stent **after expansion of the proximal end** because the detents are located *within* Heyn's catheter body and contact the stent only in the compressed configuration. Once the proximal end of Heyn's stent is deployed, it has exited Heyn's delivery device and is no longer in contact with the detents. Accordingly, Heyn's detents are incapable of performing the first function that defines of Appellants' anchoring means - "anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen." Furthermore, one skilled in the art, looking at Heyn's device including its detents, would not be motivated to adapt Heyn to achieve Appellants' anchoring means feature because Heyn is silent with respect to fixing the end of a stent after its expansion into the body lumen.

Likewise, Heyn's detents cannot perform the second function that defines the structure of Appellants' anchoring means which is to minimize relative axial movement *between the proximal end of its endoluminal device and the body lumen* during the stent's deployment. As Heyn explicitly states, the sole function of its detents is to "prevent any substantial axial travel of the stent *relative to the intermediate catheter.*" The detents of

Heyn are incapable of minimizing relative axial movement of its stent with respect to the body lumen because they are located entirely within the catheter and cannot exert any force on the stent end once that end has been deployed in the expanded state. Not only does Heyn fail to teach this function, it fails to even suggest it. Heyn is silent with respect to minimizing movement of the stent relative to the body lumen and so would provide no suggestion or motivation to arrive at Appellants' anchoring means.

Therefore, in so much as the Final Office Action relied upon Heyn as the sole prior art reference for a prima facie case of obviousness, the Office Action runs contrary to established law requiring that all of the limitations of Appellants' appealed claim 1 be taught. This rejection should be reversed.

(3) ONE OF ORDINARY SKILL IN THE ART WOULD NOT BE MOTIVATED TO COMBINE HEYN AND MARIANNE TO ARRIVE AT APPELLANTS' INVENTION RECITED IN CLAIM 1

With respect to claim 1, the Office Action alleges that Heyn discloses a stent introducer that includes a shaft with a distal tip, an inner sheath, stent, and anterograde sheath attached to the distal tip, and a retrograde sheath. OA, p 2. According to the Office Action, Heyn's anterograde sheath is axially moveable in a distal direction by distally moving the shaft. OA, p. 2. The Office Action identifies Heyn's teaching of a detent in its retrograde portion as an anchoring means. OA, p. 2. In an effort to address Heyn's admitted failure to teach an anchoring means as a balloon, the Office Action cites Marianne for its teaching of a balloon. OA, p. 2.

The Office Action proposes to modify the device disclosed by Heyn, discussed above, with the teachings of Marianne in an effort to construct Appellants' claimed invention. In support of its proposed modification, the Office Action broadly states that

> "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the anchoring detent of Heyn with a balloon, as taught by Marianne, in order

> to provide better control of the stent in the body lumen during the placement procedure."

With its vague invocation of "better control," the Office Action, however, glosses over key distinctions in the structures and goals not only between the cited references and the Appellants' invention as claimed, but also between the teachings contained in the Heyn and Marianne references it purports to combine.

Appellants' invention, as claimed in appealed claim 1, recites as its final limitation:

> **anchoring means** in at least one of the retrograde portion or the anterograde portion **for anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen**
>
> and
>
> **for minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end.**

As Appellants' have discussed, above, their "anchoring means" is a valid limitation under § 112, ¶ 6 and is entitled to patentable weight. Thus, to render Appellants' invention obvious, the proposed combination of Heyn and Marianne must teach, in addition to the earlier limitations of claim 1, one or more structural features capable of performing each of the functions associated with Appellants' anchoring means.

The Office Action cites Heyn's description of an apparatus that may be optionally equipped with one or more annular detents. The detents taught be Heyn function, essentially, as stops to "prevent any substantial axial travel of the stent *relative to the intermediate catheter.*" Heyn, col. 6, lines 47-59.[1] In the same vein, Heyn also teaches that it is desirable to minimize the coefficient of friction between its outer sheaths and its

[1] As Appellants' noted in Section E, above, these detents are incapable of performing either of the functions accorded Apellants' "anchoring means" and therefore cannot be found to have taught this limitation. Accordingly, it is assumed, for the sake of this section, that the Examiner recognized this deficiency and in fact intended to propose a combination of Heyn and Marianne as the basis for the rejecting Appellants' claim 1.

stent as compared to its stent and its intermediate catheter. Heyn, col. 5, line 63 - col. 6, line 5. Like the detents, this adaptation serves to reduce axial movement of the unexpanded end of the stent with respect to the intermediate catheter during retraction of the outer sheaths. Thus, to the extent that Heyn concerns itself with controlling stent travel, it is devoted exclusively to travel of the unexpanded end of the stent *relative to the underlying intermediate catheter*.

Turning to Marianne, the other cited reference, it teaches a traditional, distal-end first, stent deployment device equipped with a "micro-balloon" that can be inflated to pin its stent against the inner surface of its outer sheath. Marianne, Fig 3. Marianne teaches that this ability to fix the stent against the inner sheath permits an implanting surgeon to recapture the stent by pulling back on the underlying inner tube and urging it back into the catheter. Marianne, col. 3, l. 25-38. Thus, Marianne teaches fixing the unexpanded end of the stent against the outer sheath and Heyn teaches limiting travel of the unexpanded end of the stent with respect to the inner, intermediate catheter, whereas Appellants' invention claims means for minimizing movement of the stent with respect to the treated body lumen. The three approaches are therefore disparate.

Marianne teaches principal use of its balloon 20 by slight inflation "causing the primal end of the stent 7 to be firmly locked in place with respect to the inner tube 8" of the device. *See* Marianne, column 3, lines 5-9. Like Heyn, this deployment use taught by Marianne also fixes the *unexpanded* stent portion *inside* the deployment device and *against the inner surface* of its inner tube. *See* Marianne Fig. 2. Marianne also discloses secondary uses for its micro-balloon whereby (1) its additional friction is used hold the stent in place relative to the deployment device while dragging the entire apparatus in a proximal direction should some error occur during initial placement of the stent (column 3, lines 28-34) or (2) as a traditional dilatation balloon to expand the stent fully against resistance

posed by a stenosis (column 3, lines 45-53). Marianne does not teach or suggest the use of its balloon as an "anchoring means" to fix an *expanded* stent portion *outside* the deployment device *against the body lumen* during unsheathing of a remaining portion of the endoluminal device distal of the proximal end, nor could it be used in such a manner.

Marianne's description of a balloon does not suggest Appellants' anchoring means either, because Marianne does not teach minimizing the relative axial movement *between the proximal end of an endoluminal device and the body lumen*. Marianne is silent on this function. Moreover, Marianne does not teach or suggest a motivation to modify Heyn, because Marianne's teachings to pin its stent against its outer sheath are at odds with Heyn's focus on fixing its own stent with respect to its inner, intermediate catheter. Marianne's teachings are even more incompatible with Heyn's explicit interest in ensuring that the outer sheaths of its device move freely and easily. Heyn, col 5, line 63 - col. 6, line 5. Heyn's proximal and distal sheaths will not move freely and easily with one or more balloons exerting radial force(s) against them as taught by Marianne.

The Office Action asserts that it would have been obvious "to replace the anchoring detent of Heyn with a balloon, as taught by Marianne." Although the applicants disagree with this assertion, the following analysis explores the resulting structure if such a replacement were made. Marianne teaches only balloon embodiments in which the balloon is in some way fixed relative to inner tube 8. See col. 3, lines 55-57 "the pressure required to inflate the micro-balloon 20 is exerted by a fluid carried along a second lumen 22 extending along the axial lumen 4 of the inner tube 8." (Figs. 1-4); col. 4, lines 14-16 "the balloon 20 is fixed at its distal end to the inner tube 8" (Fig. 5); col. 4, lines 18-19 "inner tube 8 encloses two separated lumens . . ." (Fig. 6). Furthermore, tip 10 is also attached to inner tube 8. Thus, Marianne teaches a balloon having a location fixed relative to tip 10 and inner tube 8.

The Office Action, however, states it is obvious "to use the teachings of Marianne to adapt the inner sheath of Heyn to define an inflation lumen for the balloon of the device, as modified [in accordance with the rejection.]" Nowhere, however, does Marianne teach or suggest how to use an inner sheath as an inflation lumen where the inner sheath surrounds an inner tube that is *movable* relative to the inner sheath, as is present in the embodiment shown and describe with respect to Figs. 2 and 4 of Heyn. In all embodiments taught by Marianne, the inner sheath and the inner tube are fixed relative to one another, whereas in Heyn, the analogous elements are movable relative to one another. Such relative movability is required to perform the claimed limitation of anchoring the proximal end of the stent while the distal portion is unsheathed, given that the inner tube (connected to the tip) must be advanced distally in order to advance the anterograde sheath covering the distal portion of the stent. Were the balloon fixed relative to that inner tube, it would move the stent axially in concert with the anterograde sheath, thus defeating the limitation of minimizing relative movement between the stent and the body lumen.

Thus, applicants respectfully submit that modifying Heyn to provide a workable balloon therefore requires more than a simple combination of Heyn and Marianne. Merely providing a balloon fixed relative to the inner tube as is shown in Marianne would be unworkable, as described above. Rather, a workable balloon adapted to the Heyn design would require an inner sheath design that allows relative motion between the inner sheath and the inner core, while still providing a sealed lumen for communicating fluid to the balloon. Such an inner sheath design is outside the scope of what is taught either by Heyn or Marianne, and, in fact, would require the design taught by applicants. Because the combination of the cited references does not provide sufficient disclosure to create the structure required to meet all of the claimed limitations, the only basis for the rejection must be applicants' own specification, which is impermissible hindsight.

In summary, the Office Action has advanced no credible suggestion or motivation for either reference to adopt or be combined with the structure disclosed in the other reference to arrive at Appellants' invention as claimed. Specifically, there is no suggestion to combine features of a medial-region-first stent deployment device having an internal detents as taught by Heyn with a deployment device having a balloon as taught by Marianne, nor do the cited references provide adequate disclosure to create a structure capable of meeting all of the claimed limitations. The Office Action selectively picks and chooses features from each of the cited references for the overbroad purpose of "better control of the stent." Even *if* the two references *could* be cobbled together to form Appellants' claimed invention in a way that performs the functions claimed by the applicant, the sole motivation for the proposed combination would be Appellants' own disclosure. Such hindsight is improper as the basis for an obviousness rejection.

E. CLAIM 47

(1) ONE OF ORDINARY SKILL IN THE ART WOULD NOT BE MOTIVATED TO COMBINE HEYN AND MARIANNE TO ARRIVE AT APPELLANTS' INVENTION RECITED IN CLAIM 47

Appellants' independent claim 47 recites a further embodiment of their invention. Notably, Appellant's claim 47 includes as its last limitation an inflatable balloon mounted inside its retrograde portion.

> 47. An introducer for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration, the introducer comprising:
>
> a retrograde portion;
>
> an anterograde portion comprising a distal tip and an anterograde sheath attached proximally to the distal tip and mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder;

> a shaft attached to the distal tip and extending concentrically through a central lumen defined by the anterograde portion and retrograde portion;
>
> an endoluminal device mounted concentrically over the shaft in the central lumen and having a distal portion contained by the anterograde portion and a proximal end contained by the retrograde portion, the distal portion constrained in the compressed configuration by the anterograde sheath and adapted to expand into an expanded state as the anterograde sheath is advanced distally; and
>
> an inflatable balloon mounted radially inside the retrograde portion and sized to anchor the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration to minimize relative axial movement between the proximal end of the device and the body lumen during unsheathing of the endoluminal device distal portion.

Thus, rather than an "anchoring means," Appellants' claim 47 recites "an inflatable balloon... sized to anchor the endoluminal device proximal end against the body lumen... ."

For reasons similar to those Appellants set forth with respect to claim 1 in Section F, above, the Office Action fails to make out a prima facie case of obviousness because it does not advance a convincing suggestion or motivation to combine the teachings of Heyn with the teachings of Marianne to produce Appellants' invention as recited in claim 47. The Office Action simply states that "[it] would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the anchoring detent of Heyn with a balloon, as taught by Marianne, in order to provide better control of the stent during the placement procedure."

The Office Action's asserted motivation "to provide better control" is overbroad in that it fails to recognize the different problems faced by both Heyn and Marianne and the disparate solutions each of these references teaches. Heyn is concerned with axial migration of its stent relative to its inner catheter during deployment and teaches the use of detents and reduced friction between the stent and outer sleeves to address its perceived problem. Both of these features taught by Heyn function to *urge its stent out* of its catheter. Marianne, in contrast, is focused on *restraining its stent during* deployment and so uses a balloon to pin its stent against its outer sheath. Furthermore, as described above

with respect to claim 1, the rejection fails to recognize that without impermissibly resorting to applicants' own disclosure, the limited teachings of Heyn and Marianne are insufficient to construct a structure capable to perform the functions claimed by Applicants.

The Examiner has effectively plucked Appellants' inventive structural features from Heyn and Marianne without addressing their context within these references. One of ordinary skill in the art would not be motivated to combine these references as proposed by the Office Action because they address distinct problems with dissimilar approaches, and do not provide sufficient disclosure to construct the structure required to meet all of the claim limitations.

F. CLAIMS 31 AND 33

(1) REJECTION BASED ON THE COMBINATION OF HEYN AND EUTENEUER IS FATALLY FLAWED BECAUSE NEITHER REFERENCE TEACHES AN "ANCHORING MEANS" THAT MEETS APPELLANTS' RECITED LIMITATION

Appellants' appeal the rejection of dependent claims 31 and 33 separately because the Office Action articulates a distinct rejection relying on a new and separate reference (Euteneuer) in combination with Heyn. This rejection too is flawed. Appellants' claims 31 and 33 depend ultimately from claim 1 and incorporate all of its limitations. Therefore, they are not rendered obvious by the Office Action's proposed combination of Heyn and Euteneuer because, at a minimum, neither Heyn nor Euteneuer teach an "anchoring means" structure capable of performing the functions recited in Appellants' claim 1 under § 112, ¶ 6.

Specifically, Appellants' challenge to the Office Action's rejection of claims 31 and 33 is akin to the one articulated in Section E. That is, Heyn does not teach or suggest an anchoring means that performs the functions recited by Appellants' claim 1. In rejecting Appellants' claims 31 and 33, the Final Office Action alleges that Heyn discloses a stent

introducer that includes a shaft with a distal tip, inner sheath, stent, anterograde sheath attached to the distal tip, and a retrograde sheath. *OA, p. 2.* It also contends that Heyn teaches that the anterograde sheath and the retrograde are moveable between the positions of abutting one another and being laterally spaced from one another. *Id.* Further, Heyn's anterograde sheath is purportedly axially moveable in a distal direction by distally moving the shaft since the sheath is connected to the shaft by way of distal tip. *Id.* The Office Action then argues that Heyn also includes an anchoring means in the form of detent in the retrograde portion of preventing axial movement of the stent. *Id.*

Appellants respectfully submit, however, that neither Heyn nor Euteneuer provide a teaching or suggestion of a device feature (i.e. an anchoring means) that (1) anchors the endoluminal device proximal end after expansion of the proximal end into the proximal configuration in the body lumen and (2) minimizes relative axial movement between the proximal end of the device and the body lumen as recited in the last limitation of Appellant's claim 1:

> ...**anchoring means** in at least one of the retrograde portion or the anterograde portion **for anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen**
>
> and
>
> **for minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end**.

Heyn teaches the inclusion of "detents" in a delivery device to "prevent any substantial axial travel of the stent relative to the intermediate catheter" underlying the stent. Heyn, col. 6, lines 50-54. The detents taught by Heyn do not, indeed cannot, anchor the proximal end of its stent *after expansion of the proximal end* because the detents are located *within* Heyn's catheter body and contact the stent only in the compressed

configuration. Thus, once the proximal end of Heyn's stent is deployed, it has exited Heyn's delivery device and is no longer in contact with the detents. Accordingly, Heyn's detents are incapable of performing the first function that defines the structure of Appellants' anchoring means - "anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen." Furthermore, one skilled in the art, looking at Heyn's device including its detents, would not be motivated to adapt Heyn to achieve Appellants' anchoring means feature, because Heyn is silent with respect to fixing the end of a stent after its expansion into the body lumen.

Likewise, Heyn's detents cannot perform the second function that defines the structure of Appellants' anchoring means, which is to minimize relative axial movement *between the proximal end of its endoluminal device and the body lumen* during the stent's deployment. As Heyn explicitly states, the sole function of its detents is to "prevent any substantial axial travel of the stent *relative to the intermediate catheter*." The detents of Heyn are incapable of minimizing relative axial movement of its stent with respect to the body lumen because they are located entirely within the catheter and cannot exert any radial force. Not only does Heyn fail to teach this function, it fails to even suggest it. Heyn is silent with respect to minimizing movement of the stent relative to the body lumen and so provides no suggestion or motivation to arrive at Appellants' anchoring means.

The Office Action relies upon Euteneuer for teaching an anterograde sheath covering more than the retrograde sheath and for overlapping the two sheaths. OA, p. 4. Euteneuer discloses optional water soluble bands for anchoring portions of its prosthesis to its central core until the bands dissolve, or the use of no such bands, in which case no anchoring is provided at all. Euteneuer, col. 5, line 51 - col. 6, line 7. This disclosure does not teach or suggest an anchoring means for minimizing relative axial movement between the proximal end of the device and the body lumen during deployment of the device *from the device*

proximal end toward the device distal end, as claimed by Appellants. At best, Euteneuer and Heyn disclose features that can be used to anchor the ends of their respective prostheses inside a respective sheath and/or against a central core during deployment, but not for anchoring the proximal end *after expansion in the body lumen* during deployment from the proximal end to the distal end. By contrast, Appellants disclose and claim anchoring means capable of minimizing relative axial movement between the expanded proximal end of the device and the body lumen. *See, e.g.*, Figs. 5A and 5C in the application as filed, showing the proximal end anchored in the body lumen as the device is being deployed from the proximal end toward the distal end.

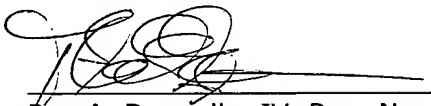
Accordingly, because the Office Action relies only upon Heyn and Euteneuer as the only prior art references to establish a prima facie case of obviousness of claims 31 and 33, the Office Action runs contrary to established law requiring that all of the limitations of Appellants' appealed claim be taught by the combination of the cited references. Because the cited references fail to meet this requirement, the rejection of claims 31 and 33 must be withdrawn.

G. CONCLUSION

The Final Office Action's rejections of Appellants' claims 1, 31, and 47 are fatally flawed because they either rely upon references that fail to teach every element of Appellants' invention as claimed or because they rely upon a combination of references for which the Office has failed to articulate a motivation to combine. The remaining non-withdrawn claims are allowable at least as being dependent upon allowable base claims. Therefore, the rejections of all of the pending claims should be reversed with instructions to issue a Notice of Allowability. Such actions are earnestly solicited.

Respectfully submitted,

RatnerPrestia



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Attachments: Related Appeals and Interferences (none)
Appellant's Evidence on Appeal (none)
Claims Appendix

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VIII. RELATED APPEALS AND INTERFERENCES

NONE.

IX. EVIDENCE APPENDIX

NONE.

X. CLAIMS APPENDIX

1. An introducer, having a retrograde portion and an anterograde portion, for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration, the introducer comprising:

a shaft having a distal tip;

an inner sheath mounted concentrically over the shaft, wherein the endoluminal device is mounted concentrically over the inner sheath in ~~a~~ the compressed configuration;

an anterograde sheath attached proximally to the distal tip, mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder; and

anchoring means in at least one of the retrograde portion or the anterograde portion for anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen and for minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end.

2. (Canceled)

3. The introducer of claim 1, wherein the anchoring means comprises an inflatable balloon at or near a proximal end of the device.

4. The introducer of claim 3, wherein the inner sheath defines a lumen connected to an inner region of the inflatable balloon for communication of a fluid to the balloon for inflation of the balloon.

5. The introducer of claim 3, wherein the inflatable balloon is mounted concentrically underneath a retrograde portion of the endoluminal device.

6. The introducer of claim 5 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath in the retrograde portion of the introducer and extending distally over the balloon and a retrograde portion of the endoluminal device.

7. The introducer of claim 6 further comprising a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer.

8. The introducer of claim 7, wherein the medial sheath has a distal end that terminates proximal of the balloon.

9. (Withdrawn) The introducer of claim 5, wherein the anterograde sheath extends proximally over the balloon and a retrograde portion of the endoluminal device.

10. The introducer of claim 1 further comprising a radial spacer for providing sufficient space between the inner sheath and the anterograde sheath to contain the endoluminal device.

11. The introducer of claim 10, wherein the radial spacer is attached proximally to the distal tip.

12. (Withdrawn) The introducer of claim 2, wherein the anchoring means comprises a holder in the anterograde portion.

13. (Withdrawn) The introducer of claim 12, wherein the holder is concentrically mounted to the inner sheath and adapted to prevent distal movement of the endoluminal device during distal advancement of the anterograde shaft.

14. (Withdrawn) The introducer of claim 13, wherein the endoluminal device has a length and the holder has a length that is less than the endoluminal device length.

15. (Withdrawn) The introducer of claim 12, wherein the anterograde sheath extends over an entire length of the endoluminal device.

16. (Withdrawn) The introducer of claim 1, wherein the anterograde sheath extends over an entire length of the endoluminal device.

17. The introducer of claim 1 further comprising:

a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and extending axially over a retrograde portion of the endoluminal device; and

a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of a proximal end of the endoluminal device.

18. (Withdrawn) The introducer of claim 17, wherein the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in the medial sheath for confining the extended portion between the retrograde sheath and the medial sheath with the retrograde sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the medial sheath.

19. (Withdrawn) The introducer of claim 2 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and wherein the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the inner sheath and the retrograde sheath for confining the extended portion between the retrograde sheath and the inner sheath with the retrograde sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the inner sheath.

20. (Withdrawn) The introducer of claim 2 further comprising:

a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath; and

a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of a proximal end of the endoluminal device;

wherein the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the medial sheath and the retrograde sheath for confining the extended portion between the retrograde sheath and the medial sheath with the retrograde sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the medial sheath.

21. (Withdrawn) The introducer of claim 2, wherein the anchoring means comprises a tether attached to a proximal end of the endoluminal device.

22. (Withdrawn) The introducer of claim 21 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and wherein the tether is attached to a portion of the inner sheath.

23. (Withdrawn) The introducer of claim 22, wherein the tether extends proximally from the device a sufficient distance to terminate outside a body lumen through which the introducer is adapted to be introduced.

24. (Withdrawn) The introducer of claim 22, wherein a proximal end of the tether is attached to means for applying an electrical current or a torsional or tensional force.

25. (Withdrawn) The introducer of claim 21 further comprising:

a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and extending axially over a proximal end of the endoluminal device; and

a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of the endoluminal device proximal end.

26. (Withdrawn) The introducer of claim 25, wherein the tether is attached to one of the medial sheath, the retrograde sheath, or the inner sheath.

27. (Withdrawn) The introducer of claim 26, wherein the tether extends proximally from the device a sufficient distance to terminate outside a body lumen through which the introducer is adapted to be introduced.

28. (Withdrawn) The introducer of claim 27, wherein the medial sheath comprises a lateral channel through which the tether extends.

29. (Withdrawn) The introducer of claim 21, wherein the anterograde sheath extends over an entire length of the endoluminal device.

30. The introducer of claim 1 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and extending axially over a proximal end of the endoluminal device.

31. The introducer of claim 30, wherein the anterograde portion extends over a greater length of the endoluminal device than the retrograde portion.

32. The introducer of claim 30, wherein the retrograde sheath and the anterograde sheath are laterally spaced from one another.

33. The introducer of claim 30, wherein the retrograde sheath and the anterograde sheath laterally overlap one another.

34. (Withdrawn) A method for deployment of an endoluminal device in a distal location in a body lumen from a proximal location, the method comprising the steps of:

(a) inserting an introducer into the body lumen, the introducer comprising a retrograde portion; an anterograde portion; a shaft having a distal tip; an inner sheath mounted concentrically over the shaft with the endoluminal device mounted concentrically over the inner sheath; and an anterograde sheath proximally attached to the shaft distal tip, mounted over the endoluminal device in the anterograde portion of the introducer, and axially moveable relative to the inner sheath;

(b) aligning the introducer in a deployment location;

(c) extending the shaft to distally advance the anterograde sheath to deploy at least a proximal portion of the endoluminal device; and

(d) removing the introducer from the body lumen.

35. (Withdrawn) The method of claim 34, wherein the introducer further comprises anchoring means in the anterograde portion for anchoring the endoluminal device during deployment of the device from a proximal end to a distal end of the device, the method comprising aligning the proximal end of the device with the deployment location in step (b) and confining the endoluminal device between the anchoring means and the advancing anterograde sheath in step (c).

36. (Withdrawn) The method of claim 34, wherein the introducer further comprises anchoring means in the retrograde portion for anchoring the endoluminal device during deployment of the device from a proximal end to a distal end of the device, the method comprising aligning the proximal end of the device with the deployment location in step (b), anchoring the proximal end during step (c), and releasing proximal end prior to or concurrently with step (d).

37. (Withdrawn) The method of claim 36 wherein the anchoring means comprises an inflatable balloon, and the method further comprises inflating the balloon prior to step (c) and deflating the balloon after step (c).

38. (Withdrawn) The method of claim 37 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and extending axially over the proximal end of the endoluminal device and the balloon, the method further comprising retracting the retrograde sheath prior to inflating the balloon, and inflating the balloon to anchor the proximal end of the endoluminal device against the body lumen.

39. (Withdrawn) The method of claim 37 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and extending axially over the proximal end of the endoluminal device and the balloon, the method further comprising inflating the balloon to anchor the proximal end of the endoluminal device against the retrograde sheath and then retracting the retrograde sheath after deflating the balloon.

40. (Withdrawn) The method of claim 36, wherein the anchoring means comprises a tether releasably attached to the proximal end of the endoluminal device, the method comprising separating the tether from the endoluminal device prior to step (d).

41. (Withdrawn) The method of claim 40, wherein the introducer further comprises a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath; a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of the proximal end of the endoluminal device; and the anchoring means comprises a tether releasably attached to the proximal end of the endoluminal device and non-releasably attached to a distal end of the retrograde sheath, the method comprising retracting the retrograde sheath to separate the tether from the endoluminal device prior to step (d).

42. (Withdrawn) The method of claim 41, wherein a portion of the retrograde sheath extends over a portion of the endoluminal device, the method comprising retracting the portion of the retrograde sheath extending over the endoluminal device prior to step (c).

43. (Withdrawn) The method of claim 40, wherein the introducer further comprises a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and the anchoring means comprises a tether releasably attached to the proximal end of the endoluminal device and non-releasably attached the inner sheath, the method comprising separating the tether from the endoluminal device during retraction of the introducer in step (d).

44. (Withdrawn) The method of claim 36, wherein the introducer further comprises a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath; a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of the proximal end of the endoluminal device; and the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the medial sheath and the retrograde sheath, the method further comprising releasably confining the extended portion between the retrograde sheath and the medial sheath until after step (c), and then retracting the retrograde sheath relative to the medial sheath a distance sufficient to release the extended portion from the notch.

45. (Withdrawn) The method of claim 44, wherein the retrograde sheath extends over a retrograde portion of the endoluminal device, the method comprising retracting the portion of the retrograde sheath extending over the endoluminal device prior to step (c).

46. (Withdrawn) The method of claim 36, wherein the introducer further comprises a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the inner sheath and the retrograde sheath, the method further comprising releasably confining the extended portion between the retrograde sheath and the inner sheath until after step (c), and then retracting the retrograde sheath relative to the inner sheath sufficient to release the extended portion from the notch.

47. An introducer for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration, the introducer comprising:

a retrograde portion;

an anterograde portion comprising a distal tip and an anterograde sheath attached proximally to the distal tip and mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder;

a shaft attached to the distal tip and extending concentrically through a central lumen defined by the anterograde portion and retrograde portion;

an endoluminal device mounted concentrically over the shaft in the central lumen and having a distal portion contained by the anterograde portion and a proximal end contained by the retrograde portion, the distal portion constrained in the compressed configuration by the anterograde sheath and adapted to expand into an expanded state as the anterograde sheath is advanced distally; and

an inflatable balloon mounted radially inside the retrograde portion and sized to anchor the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration to minimize relative axial movement between the proximal end of the device and the body lumen during unsheathing of the endoluminal device distal portion.

48. (Withdrawn) The introducer of claim 47 further comprising an inner sheath mounted concentrically over the shaft underneath the endoluminal device, the inner sheath defining a lumen connected to an inner region of the inflatable balloon for communication of a fluid to the balloon for inflation of the balloon, wherein the retrograde portion comprises a proximally retractable retrograde sheath mounted concentrically over the shaft and the inner sheath and extending distally over the balloon and a retrograde portion of the endoluminal device.

49. (Withdrawn) A method for deployment of an endoluminal device in a distal location in a body lumen from a proximal location, the method comprising the steps of:

(a) inserting an introducer into the body lumen having a lumen wall, the introducer comprising a retrograde portion, an anterograde portion comprising a distal tip and an anterograde sheath attached proximally to the distal tip, a shaft attached to the distal tip and extending concentrically through a central lumen defined by the anterograde portion and retrograde portion, an endoluminal device mounted concentrically over the shaft in the central lumen and having a distal end contained by the anterograde portion and a proximal end contained by the retrograde portion, an inflatable balloon mounted inside the retrograde portion for anchoring the endoluminal device during deployment of the device, and a proximally retractable retrograde sheath extending distally over the balloon and the proximal end of the endoluminal device;

(b) aligning the proximal end of the endoluminal device in a deployment location;

(c) retracting the retrograde sheath to allow a proximal portion of the endoluminal device including the proximal end to deploy;

(d) inflating the balloon to compress the proximal portion of the endoluminal device against the lumen wall; and

(e) extending the shaft to distally advance the anterograde sheath to deploy a remaining portion of the endoluminal device.

50. (Withdrawn) The introducer of claim 5, wherein the anchoring means further comprises a holder in the anterograde portion concentrically mounted to the inner

sheath and adapted to prevent distal movement of the endoluminal device during distal advancement of the anterograde shaft.

51. The introducer of claim 30, wherein the retrograde sheath and the anterograde sheath abut one another.